LUCKY SUPERSOFT MAXIMUM STRENGTH- hydrocortisone cream Anicare Pharmaceuticals Pvt. Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Lucky HC Cream 1

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

■ temporarily relieves itching associated with minor skin irritations and rashes due to: ■ eczema ■ psoriasis ■ poison ivy, oak, sumac ■ insect bites ■ detergents ■ jewelry ■ cosmetics ■ soaps ■ seborrheic dermatitis ■ temporarily relieves external anal and genital itching ■ other uses of this product should be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

■ in the genital area if you have vaginal discharge. Consult a doctor ■ for the treatment of diaper rash. Consult a doctor

When using this product

■ avoid contact with eyes ■ do not use more than directed unless told to do so by a doctor ■ do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

■ the condition worsens, symptoms persist for more than 7 days or clear up and occur again wihin a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor ■ rectal bleed occurs

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

■ **for itching of skin irritation, inflammation and rashes:** ■ adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily ■ children under 2 years of age: ask a doctor

for external anal and genital itching, adults: ■ when practical, clean the affected area with mild soap and water and rinse thoroughly ■ gently dry by patting or blotting with toilet tissue or a soft cloth before applying ■ apply to affected area not more than 3 to 4 times daily ■ children under 12 years of age: ask a doctor

Other information

do not use if tube seal under cap is broken, missing or if the tube tip is cut prior to opening

Inactive ingredients

aloe barbadensis leaf juice, aluminum sulfate, beeswax, calcium acetate, cetearyl alcohol, dextrin, glycerin, maltodextrin, methylparaben, mineral oil, petrolatum, propylparaben, sodium cetearyl sulfate, sodium lauryl sulfate, water

Package Label



LUCKY SUPERSOFT MAXIMUM STRENGTH hydrocortisone cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
ALUMINUM SULFATE (UNII: 34S289N54E)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CALCIUM ACETATE (UNII: Y882YXF34X)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
ICODEXTRIN (UNII: 2NX48 Z0 A9 G)			
GLYCERIN (UNII: PDC6A3C0OX)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
MINERAL OIL (UNII: T5L8T28FGP)			
PETROLATUM (UNII: 4T6H12BN9U)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
WATER (UNII: 059QF0KO0R)			

Packaging					
:	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1 NDC:47046-176-01	14 g in 1 TUBE; Type 0: Not a Combination Product	0 1/3 1/2 0 15		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part348	0 1/31/20 15			

Labeler - Anicare Pharmaceuticals Pvt. Ltd. (916837425)

Revised: 12/2020 Anicare Pharmaceuticals Pvt. Ltd.